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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,198	11/30/2000	Pierre L. Triozzi	CIR 2-005	2840

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	**PAPER NUMBER**
1648	5

DATE MAILED: 02/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/727,198	Applicant(s) TRIOZZI ET AL.	
	Examiner Ulrike Winkler, Ph.D.	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however; may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-5 and 8, drawn to a factor ≥ 50 kDa derived from the supernatant of lymphocytes, classified in class 530, subclass 350.
2. Claims 6, 7, 62 and 63, drawn to drawn to a factor 70-80 kDa derived from the supernatant of lymphocytes, classified in class 530, subclass 350.
3. Claims 9-20, drawn to a method of isolating a factor ≥ 50 kDa derived from the supernatant of lymphocytes, classified in class 530, subclass 415.
4. Claims 21-32, drawn to a method of isolating a factor 70-80 kDa derived from the supernatant of lymphocytes, classified in class 530, subclass 415.
5. Claims 33-34, drawn to a method of enhancing the activity of an enzyme utilizing a factor ≥ 50 kDa derived from the supernatant of lymphocytes, classified in class 424, subclass 85.1.
6. Claim 35, drawn to a method of enhancing the activity of an enzyme utilizing a factor 70-80 kDa derived from the supernatant of lymphocytes, classified in class 424, subclass 85.1.
7. Claim 36, drawn to a method of enhancing the activity of tamoxifen utilizing a factor ≥ 50 kDa derived from the supernatant of lymphocytes, classified in class 435, subclass 4.
8. Claim 37, drawn to a method of enhancing the activity of tamoxifen utilizing a factor 70-80 kDa derived from the supernatant of lymphocytes, classified in class 435, subclass 4.

9. Claims 38-42, drawn to a method of treating an HIV infected patient with a factor ≥ 50 kDa derived from the supernatant of lymphocytes, classified in class 424, subclass 208.1.

10. Claims 42-44, drawn to a method of treating an HIV infected patient with a factor 70-80 kDa derived from the supernatant of lymphocytes, classified in class 424, subclass 208.1.

11. Claims 45 and 47-51, drawn to a method of treating a patient inflicted with a disease using a factor ≥ 50 kDa derived from the supernatant of lymphocytes, classified in class 424, subclass 9.2.

12. Claims 46 and 52-56, drawn to a method of treating a patient inflicted with a disease using a factor 70-80 kDa derived from the supernatant of lymphocytes, classified in class 424, subclass 9.2.

13. Claims 57-61 and 64, drawn to a factor used for treating a patient inflicted with a disease which leads to immunosuppression the factor is ≤ 50 kDa derived from the supernatant of lymphocytes, classified in class 424, subclass 85.2.

15. Claims 65-66, drawn to a factor used for treating a patient inflicted with a disease which leads to immunosuppression using a factor ≤ 50 kDa that is a multimer derived from the supernatant of lymphocytes, classified in class 424, subclass 85.2.

For each of groups 1-6 and 11-14 above, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects one of the inventions of groups 1-6 and 11-14, election is further required for inventions (A)-(F):

A. Acute or persistent viral infection (further species restriction required, see below)

B. Bacterial infection (further species restriction required, see below)

C. Autoimmune disease (further species restriction required, see below)

D. Parasite infection

E. Cancer

F. Chronic Fatigue Syndrome

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(F) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of A-F represent different diseases, which are caused by different pathogens that contain structurally different polypeptides. Therefore, where structural identity is required, as enhancing activities or different binding, the different sequences encoded by the different pathogens have different effects.

Groups 1, 2, 13 and 14 are compositions and are distinct from groups 3-12 which are drawn to methods. Groups 1, 2, 13 and 14 are compositions and each is distinct from the other because they contain different materials. Groups 1, 2, 13 and 14 comprises an isolated factors

from the supernatant of lymphocyte cells, these factors are proteins and are made up of amino acids. These factors are distinct from each other based their different size and whether or not they are made up of multimers. Though there may be overlap for these groups, the search for one group will not be coextensive with that of the other group.

Groups 3-15 are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not expected to be the same. The method protocols treat different diseases or cell populations utilizing the different isolated factors. Though there may be overlap for these groups, the search for one group will not be coextensive with that of the other group.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed inventions listed in **A-C** above found in the invention groups 1-6 and 11-14:

If the invention (**A**) above, drawn to acute or persistent viral infection, is elected a further species election drawn to a single viral family is also required:

A1. picornaviruses (hepatitis)
A2. togaviruses
A3. paramyxoviruses (measles, canine distemper virus)
A4. orthomyxoviruses
A5. rhandoviruses
A6. reoviruses

A7. retroviruses (HIV)
A8. bunyaviruses
A9. coronaviruses
A10. arenaviruses
A11. panoviruses
A12. papoviruses
A13. adenoviruses
A14. herpesviruses
A15. poxviruses
A16. dengue virus (flaviviurses)

If the invention (**B**) above, drawn to a bacterial infection, is elected a further species election drawn to a single bacterial pathogen is also required:

B1. tuberculosis (*Mycobacterium tuberculosis*)
B2. leprosy (*Mycobacterium leprae*)

If the invention (**C**) above, drawn to an autoimmune disease, is elected a further species election drawn to a single bacterial pathogen is also required:

C1. rheumatoid arthritis
C2. multiple sclerosis

These species are distinct because the pathological conditions differ in etiologies and therapeutic end points.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

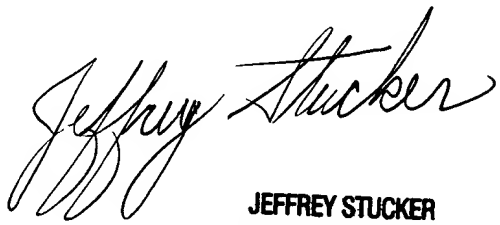
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.



JEFFREY STUCKER
PRIMARY EXAMINER